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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/397,225	PERRICAUDET ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,9-30 and 33-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,9-30 and 33-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Interference

Interference Nos. 104824, 104828, and 104830 have been terminated by decisions adverse to applicant. Interference No. 104829 has been terminated by a decision favorable to applicant. *Ex parte* prosecution is resumed.

Claims 1-3, 9, 11-18, 28, 30, 34, 35, and 40-42, as to which judgments adverse to Applicant have been rendered, stand finally disposed of in accordance with 37 CFR 41.127. It is suggested that these claims be cancelled.

The previously indicated allowability of claims 6, 10, 19-27, 29, 33, and 36-39 is withdrawn in view of the new rejections set forth below. Whether the grounds of the rejections set forth below also apply to one or more of claims 1-3, 9, 11-18, 28, 30, 34, 35, and 40-42 is moot, since these claims stand finally disposed of, and consequently, these claims have not been included in the rejections.

The following allowable claims are suggested for the purpose of an interference under 37 CFR 41.202(c):

43. A human embryonic kidney 293 cell line, which in addition to the human adenovirus Ad5 genes present in a human embryonic kidney 293 cell itself, comprises integrated into its genome additional adenoviral genes,

wherein the additional adenoviral genes are E4 genes from a human group C adenovirus under control of an inducible promoter, and expression of the E4 genes would complement defective replication of a group C adenovirus whose genome has a deleted E4 region, and

wherein the additional adenoviral genes and the human Ad5 genes are the only adenoviral genes in the cell line.

Claims 76-80 and 83 of Applicant's co-pending application 10/301,085 are considered unpatentable over this suggested claim, i.e. they are not patentably distinct.

The following claim is considered allowable and directed to a separate patentable invention from the claim suggested above:

44. A human embryonic kidney 293 cell line, which in addition to the human adenovirus Ad5 genes present in a human embryonic kidney 293 cell itself, comprises integrated into its genome additional adenoviral genes,

wherein the additional adenoviral genes consist of:

1) E4 genes from a human group C adenovirus under control of an inducible promoter, and expression of the E4 genes would complement defective replication of a group C adenovirus whose genome has a deleted E4 region; and

2) an E2 gene from a human group C adenovirus, which E2 gene encodes the 72K protein and is under control of an inducible promoter, and

wherein the additional adenoviral genes and the human Ad5 genes are the only adenoviral genes in the cell line.

If claims 19-27 and 33 were amended as suggested below, they would be considered unpatentable over this suggested claim.

The suggested claims must be copied exactly, although other claims may be proposed under 37 CFR 41.202.

Applicant should make the suggested claim in reply to this Office action. Failure to do so will be considered a disclaimer of the subject matter of this claim under the provisions of 37 CFR 41.202(c).

Claim Objections

Claims 6, 10, 19-27, 29, and 33 are objected to because of the following informalities. The claims depend from claims that stand finally disposed of in accordance with 37 CFR 41.127. Claims 6, 10, and 19 should be rewritten in independent form.

Appropriate correction is required.

In Paper No.116 of Interference No. 104830 (entered into the instant application 2/24/04 as Paper No. 51) at pages 27-29, the Board held that claims 21, 22, and 33, which recite that the cell line of claim 19 comprises E4 complementing sequences, do not properly depend from claim 19 due to the amendment of claim 1, from which claims 19, 21, 22, and 33 depend, where the vector is deficient in E2 genes but not E4 genes.

Upon further review, claim 19 requires that the cell line comprise those adenoviral genes necessary to complement the deficiencies in a vector of claim 1, i.e. it must comprise E1 and E2

complementing sequences. Claims 21, 22, and 33 were deemed improperly dependent from claim 19, because they require E4 complementing sequences, whereas the vector of claim 1, as amended, retains the E4 genes and E4 complementing sequences in the cell line would be unnecessary. However, claim 19 does not limit the adenoviral sequences to those required for complementation of the vector of claim 1; it simply must comprise them, and as such may further comprise other elements. As dependent claims, claims 21, 22, and 33 must include all the limitations of claims from which they depend, and these claims do not exclude the presence of E1 and E2 genes from the cell line. Thus, claim 19 embraces a cell line that further comprises adenoviral genes in addition to the E1 and E2 genes, e.g. E4 genes as in claims 21, 22, and 33. Therefore, claims 21, 22, 33 (and 24) do properly depend from claim 19.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 19-26, 29, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claims 10 and 29, claim 1 was amended on 1/25/03 following the order by the Board of Interferences in Interference No. 104,824 (Paper No. 66, filed 1/31/03) to enter

Proposed Amendment C attached to Joint Preliminary Motion 1 (Paper No. 61, filed 1/25/03). The amendment entered 1/25/03 introduced new matter into claims 10 and 29 by removing the limitation from claim 1 that the adenoviral vector could have a deletion of E4 genes, but not E2 genes. As a result, claims 10 and 29 are now directed to a replication defective adenoviral vector having E1, E2, and E3 genes, but not E4 genes, and L5 rendered non-functional by deletion. In contrast, original claim 10 had been directed to a replication defective adenoviral vector having E1, E3, and E4 genes and L5 rendered non-functional by deletion. The original specification does not describe the particular embodiment that had been claimed originally in claim 10, i.e. original claim 10 constitutes its own description. There is no support in the original specification for the particular embodiment now the subject of claim 10, especially the deletion of E2 genes, but not E4 genes, and deletion of at least L5 specifically out of L1-L5.

With respect to claims 19-26 and 33, claim 19 was amended on 5/8/96 to recite that one of the adenoviral genes necessary to complement loss-of-function of E1 genes and E2 or E4 genes in an adenoviral vector are under control of an inducible promoter. Original claim 19 did not require any complementing sequence to be under control of an inducible promoter. With the amendment to claim 1 on 1/25/03, claim 19 now requires that one of the adenoviral sequences for complementing E1 or E2 be under control of an inducible promoter. As written, claim 19 reads on embodiments where the E1 complementing sequence are under control of an inducible promoter, and the E2 complementing sequence may or may not be under control of an inducible promoter. This subject matter embraced by claim 19 is new matter.

Applicant did not indicate how or where the original disclosure supported this amendment, in the Reply filed 5/8/96. The original specification and claims did not describe

embodiments of complementing cell lines where an E1 complementing sequence is under control of an inducible promoter. The only places where the original disclosure describes placing complementing sequences under control of an inducible promoter are at page 20, line 25, to page 21, line 34 and page 25, lines 28-34, of the specification and claims 24 and 25. It is E2 and E4 complementing sequences alone that are described as being under control of an inducible promoter. Page 21 describes 293 cell lines, which has the E1 region under control of E1 promoters, and gm DBP6 cells with E1A and E1B under control of their own promoters. There is no mention in the specification of placing E1 genes under control of an inducible promoter. Thus, claim 19 and its dependent claims 20-26, which embrace embodiments where at least the E1 complementing sequence is under control of an inducible promoter, are new matter. Claim 27 is not rejected on these grounds since 293 cells have E1 genes under control of there own promoters, and the E2 complementing sequence must therefore be the one under control of an inducible promoter.

Claims 6, 10, 19-27, 29, 33, and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record set forth in Paper No. 51 on pages 58-72, as applied to claims 34 and 42, and the additional reasons set forth below. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Paper No. 51 is a copy of Paper No. 116 of Interference No. 104830 entered into the instant application on 2/24/04. The contents of pages

58-72 of Paper No. 51 of the instant application are incorporated herein by reference as grounds of rejection.

During the '830 interference, Wang had moved for judgment that claims 1-3, 9, 12-28, 30, 33-35, and 40-42 were unpatentable under 35 USC 112, first paragraph, as not being enabled throughout their scope. The motion was granted with respect to claims 34 and 42, but dismissed as being moot with respect to the remaining claims because there was no interference-in-fact between the remaining claims and any claims in the Wang application. See pages 58-72 of Paper No. 51. Nonetheless, these grounds for lack of an enabling disclosure on how to make the vectors of claims 34 and 42 also apply to the vectors of claims 6, 10, 29, and 36-39 and the cell lines of claims 19-27 and 33, as explained below.

Claim 34 is directed to a replication-defective adenoviral vector that comprises the cis-elements necessary for replication and the E2 region as the only early region, i.e. the E1 and E4 regions, which are required for replication, and the E3 region, which is dispensable for replication, are absent. The claim embraces vectors where additional adenoviral genes, e.g. L1-L5, are non-functional. Claim 42 is directed to a replication-defective adenoviral vector whose replication requires complementation of an essential gene in E2A and E4, and optionally E1 as well. The vector must comprise at least one functional late or early gene region. However, the claim embraces vectors where there is only one such functional late or early gene region retained, e.g. an E3 gene, a non-essential E4 gene, or one of L1-L5, and where one or both E2B genes are also non-functional.

Claims 6, 10, and 29 are directed to a vector that requires complementation of non-functional E1 genes and E2 genes, but not E4 genes. The claims embrace vectors where

additional adenoviral genes are deleted, e.g. L1-L5 (claim 6) and L1 (claims 10 and 29). The E2 region is divided into the E2A region, which encodes the 72K protein (a.k.a. double-strand binding protein), and the E2B region, which encodes the DNA polymerase and preterminal protein, i.e. there are three E2 genes. By reciting "E2 genes" in claim 1, the vector of claims 6, 10 and 29 must have at least two of the E2 genes non-functional by deletion, which requires at least one of the E2B genes to be rendered non-functional by deletion. The E2B region substantially overlaps the late genes L1-L4, and the MLP promoter from which the L1-L5 genes are expressed. Thus deletion in E2B genes may also involve deletions of late genes as well, as in claims 6, 10, and 29. Claims 36-39 broadly embrace recombinant adenovirus where E2 genes and late genes are non-functional, in addition to the non-functional E1 and E4 genes recited.

Consequently, the subject matter of claims 6, 10, 29, 36-39 substantially overlaps that of claims 34 and 42 with respect to essential adenoviral early and late genes that may be non-functional. Claim 42 embraces embodiments wherein the vector has one or more non-functional E2B genes in addition to E2A and/or one or more non-functional late genes that would require complementation in a cell line, as in claims 6, 10, and 29. Claim 34 embraces embodiments wherein the vector has one or more non-functional late genes that would require complementation in a cell line, as in claims 6, 10, and 29. In addition, claims 6, 10, 29, 34, 36-39, and 42 embrace adenoviral vectors based upon adenoviruses isolated from any animal species or of any type. It is these embodiments embraced by claims 34 and 42 that were held to be not enabled by the specification in Paper No. 116 of the '830 interference, i.e. the specification did not enable making vectors based on adenovirus that were not human subgroup C adenoviruses like Ad2 or Ad5, and did not enable making vectors that were deleted in E2B

genes, the MLP promoter, and/or late genes L1-L5, or that were deleted in protein IX, where the size of the vector is less than 75% of the wild-type genome (less than 25 kb).

In large part, the lack of enablement of the full scope of the claims 34 and 42 was due to the lack of an enabling disclosure on making helper virus or complementing cells required to replicate or propagate adenoviral vectors that were not human subgroup C adenoviral vectors or where the vector had a non-functional E2B gene(s), late gene(s), MLP or protein IX gene. Claims 19-27 and 33 require that the cell lines be able to complement a replication deficient adenoviral vector derived from adenoviruses isolated from any animal species or from any type. In addition, the cell lines must complement adenoviral vectors deficient in E1 and in multiple E2 genes, at least one of which must be an E2B gene. The cell lines also may be required to complement the E2A gene and one of the two E2B genes, both E2B genes, or all three E2 genes, as well as one or more of the late genes. Consequently, the grounds in Paper No. 51 for which the specification was held not to enable making the vectors of claims 34 and 42, where multiple E2 genes and/or late genes are non-functional, necessarily also applies to the cell lines required to make such vectors, i.e. the lack of an enabling disclosure for making such vectors was due in part to lack of an enabling disclosure for making the cell lines that are the subject matter of claims 19-27 and 33.

In addition to the grounds of rejection from Paper No. 51, claims 19, 22, 23, 25, and 33 embrace embodiments wherein the E2 genes are not under control of an inducible promoter, because the claim allows that the E1 genes may be the complementing genes under control of an inducible promoter. Cell lines with E2 genes under control of an inducible promoter, which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled

by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). As stated in the specification at page 20, lines 25-27, the E2 and E4 genes are placed under control of inducible promoters, as in claims 20, 24, and 26, because the E2 gene products are cytotoxic.

The rejection of claims 36-39 would be overcome by limiting non-functional adenoviral genes to the non-functional E4 genes, and optionally to non-functional E1 and E3 genes, i.e. all other adenoviral genes are present in the vector.

The rejection of claims 19-27 and 33 would be overcome by limiting claim 19 to a human cell line comprising adenoviral E1 genes under control of their own promoters and an adenoviral E2 gene encoding the 72K protein under control of an inducible promoter, and optionally, adenoviral E4 genes under control of an inducible promoter, wherein the adenoviral E1 genes, the adenoviral gene encoding the E2 72K protein, and optional E4 genes are from a human subgroup C adenovirus, and wherein the cell line does not comprise any adenoviral genes other than the E1 genes, the E2 gene encoding the 72K protein, and the E4 genes. This last exclusion limitation necessitates including the E4 genes in the base claim as an option. If adopted, some of claims 19-27 will become duplicates of one another. Currently, claim 19 does not embrace the subject matter proposed above, since the cell line would complement a deficiency in only one E2 gene, specifically the E2 gene that encodes the 72K protein.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 6, 10, 19, 20, 23, 25-27, 29, and 36-39 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 34, 36, 45-50, 52, and 56-59, respectively, of copending Application No. 10/301,085. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Instant claims 1-3, 6, 9-20, 23, 25-30, and 34-42 are identical or essentially identical to claims 31-62, respectively, of the '085 application. Since claims 1-3, 9, 11-18, 28, 30, 34, 35, and 40-42 stand finally disposed of in accordance with 37 CFR 41.127 and are unpatentable to Applicant, they have not been included in this rejection.

Claims 1-3, 6, 9-20, 23, 25-30, and 34-42 of this application conflict with claims 31-62 of Application No. 10/301,085. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

It is suggested that claims 31-62 in the '085 application be cancelled.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21, 22, 24 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45, 46, 62, 76-80, 83 and 84 of copending Application No. 10/301,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 21, 22, 24, and 33 are directed to cell lines that comprise adenovirus genes necessary to complement an adenoviral vector having non-functional E1 and E2 genes (from claim 19 in its dependence on claim 1) and further comprise adenoviral E4 gene(s), e.g. ORF6 and ORF6/7, under control of an inducible promoter. Claims 45 and 46 of the '085 application are identical to instant claims 19 and 20, i.e. the cells comprise at least adenoviral E1 and E2 complementing sequences. The cell lines of claims 76-80 and 83 of the '085 application are similar to those of claims 45 and 46, except the cells comprise at least adenoviral E1 and E4 complementing sequences. While the '085 application does not explicitly claim a cell line that complements loss-of-function deletions in E1, E2 and E4 in an adenoviral vector, the supporting disclosure of these cell lines in the '085 specification certainly does. Furthermore, claim 84 of the '085 application requires at least E2 and E4 complementing sequences, and claim 62 is directed to an adenoviral vector that requires complementation of defects in at least the E2A and E4 regions, and optionally the E1 region as well. For embodiments wherein the vector lacks essential genes in all three regions, a

complementing cell line would have to have adenoviral complementing sequences from E1, E2, and E4, as in instant claims 21, 22, 24, and 33. Consequently, the subject matter of instant claims 21, 22, 24, and 33 is obvious over the claims of the '085 application because its claim 62 would necessitate using a cell line of any of its claims 45, 46, 76-80, 83 and 84, wherein complementing adenoviral sequences for the region not mentioned in each of the claims are also present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant is advised that should claim 21 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
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Art Unit 1632